IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC.

MDL NO. 2327

PELVIC REPAIR SYSTEMS
PRODUCTS LIABILITY LITIGATION

This Document Relates To All Cases

PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION FOR ORDER REGULATING PLAINTIFFS' COUNSEL'S *EX PARTE* CONTACTS WITH TREATING PHYSICIANS

COME NOW, Plaintiffs and file their Response in Opposition to Defendants Johnson & Johnson and Ethicon, Inc.'s "Motion for Order Regulating Plaintiffs' Counsel's Ex Parte Contacts with Treating Physicians" (Dkt. No. 1707), and show the following:

Statement of Factual and Procedural Background

The Defendants' present motion, which seeks to limit Plaintiffs' counsel's right to meet with Plaintiffs' treating physicians, is merely a rehash of the same arguments made by Bard in MDL 2187 more than three years ago. (*See*, Case No. 2:10-md-2187, Dkt. No. 287 (Bard letter brief seeking to limit plaintiffs' counsel's "ex parte" communication with treating physicians)). In its motion three years ago, Bard made nearly the identical arguments of unfairness and improper witness "coaching," and cited to many of the same cases that were alleged to support its position as Ethicon relies upon here. *Id.* These issues were briefed and argued orally before the Hon. Mary E. Stanley on August 2, 2012. (*See*, Magistrate Hearing Transcript of August 2, 2012 in MDL 2187 attached hereto as **Exhibit 1**). During the hearing, in which Bard's attorneys decried the use of "confidential" corporate documents, and claimed that treating physicians were

being improperly persuaded during lengthy meetings with Plaintiffs' attorneys, Judge Stanley made several instructive observations:

> I think all agree that there is no provision in the Federal Rules of Civil Procedure, Federal Rules of Evidence, or the local rules, which has anything to say about this and, in fact, from my own trial preparation experience, my experience on the bench, lawyers would be derelict if they did not interview their witnesses before they took their testimony and if they did not show them relevant documents. I find what the plaintiffs have done, particularly and specifically as set forth in the [plaintiff's implanting physician] Barbee deposition, to have been entirely proper. It appears to have been a very professional deposition….So I will deny that motion for a protective order with respect to setting forth limitations on the plaintiffs in their ex parte discussions with plaintiffs' treating physicians.

(**Exhibit 1**, 21:12-19; 22:21-23).

The day after hearing oral argument on the issue, Judge Stanley issued a written order denying Bard's attempt to limit Plaintiffs' ability to communicate with their physicians. (Case No. 2:10-md-2187, Dkt. No. 290 (Pretrial Order #48), a copy of which is attached hereto as **Exhibit 2**)). In her Order (pp. 3-4), Judge Stanley ruled as follows:

> After due consideration of the parties' arguments and the cases cited by them, the court declines to impose limits on plaintiffs' counsel's *ex parte* communications with plaintiffs' treating physicians. Neither a statute nor a rule suggests that such limits are appropriate; in fact it is accepted that attorneys are expected to prepare their witnesses for the rigors of giving testimony. As this MDL develops, it becomes more apparent that the plaintiffs are pursuing multiple theories, including those of negligent design and negligent failure to warn. It is important to develop the facts as to what the defendants knew about their products' effects on women's pelvic organs and when they knew those facts. Contents of corporate documents and statements of sales representatives to treating physicians and surgeons are appropriate areas of inquiry as to whether full disclosure would have changed a doctor's mind about implanting a pelvic mesh product.

On August 15, 2014, Bard urged that this Court "revisit" the issue of Plaintiffs' "ex parte" communications with treating physicians in light of the written deposition question process that was in place in Bard (but not here in this MDL). (A copy of the August 15, 2014 Magistrate hearing is attached hereto as **Exhibit 3**). This Court declined Bard's efforts to impose

limitations on plaintiffs' ability to communicate with doctors, citing Judge Stanley's prior ruling on this issue, stating:

> THE COURT: If you're asking me not to allow the plaintiffs' attorneys to speak with the physicians prior to the deposition, then Judge Stanley's already ruled on that. And I'm not going to change her ruling on that….
>
> THE COURT: Well, you know -- I think as far as speaking to -- as far as ex parte contact with the physician, the traditional ex parte contact, I don't think that there's anything I would do to change that.
> …
> And I don't think that I can change Judge Stanley's ruling. I mean, that is – there would be no reason to do that. I mean, I think that is the law of the case as it stands right now.

(**Exhibit 3**, 33:15-18; 35:2-5; 35:10-14).

Like Bard's after-the-fact attempt in the wave process last year, Ethicon's attempt to undo Judge Stanley's sound ruling should similarly fail. The Ethicon MDL (along with the AMS and Boston Scientific MDLs, and later the Coloplast, Cook, and Neomedic MDLs) was transferred to this Court by the JPML specifically for the reason that coordination of these cases with the already pending Bard MDL would promote judicial economy and avoid inconsistent pretrial rulings addressing common legal issues. Judge Stanley's ruling has been the law of the case in these MDLs for more than three years, and has governed literally hundreds of doctor depositions taken to date in the various pelvic mesh MDLs. All of the same arguments raised by Ethicon here were thoughtfully considered and addressed by Judge Stanley, and Ethicon offers no reasonable basis to revisit or alter this ruling that has governed this litigation for more than three years, other than perhaps the fact that it does not like the ruling.

It is instructive to note that the alleged instances of "impropriety" asserted in support of Ethicon's motion occurred in plaintiff-physician meetings prior to depositions that were taken in 2013 (one of the depositions, discussed below, was taken in June 2014 – in a case that is now

resolved and dismissed). (Dkt. No. 1707, pp. 3-5 and n. 4).[1] However, Ethicon has never filed any motion relating to this established practice in these MDLs, and furthermore has never made any allegation of surprise, prejudice, bias or unfairness with respect to any one of these depositions or any of these cases. The only 2014 deposition mentioned in Ethicon's brief (Carol Dehasse, M.D., Ex. 6 to Ethicon's Davis Declaration), was taken in the *Bellew* case (2:13-cv-22473). Ethicon filed dozens of pre-trial motions in *Bellew*, including dispositive motions, *Daubert* motions and motions in limine, among others. Ethicon's lawyers and Plaintiffs' counsel spent days going back-and-forth on deposition cuts in *Bellew*, and spent several hours on November 25, 2014 in a deposition cut hearing before this Court. Tellingly, however, no motion was filed and no issue was otherwise ever raised in *Bellew* regarding anything untoward or unfair about any deposition taken in that case. After five days of trial testimony, the *Bellew* case resolved confidentially, and the case was later voluntarily dismissed with prejudice. Respectfully, if anything unfair or prejudicial had occurred in the context of any deposition taken two years ago – or that was taken in a case that went to trial before being resolved and dismissed – it would have been raised long before now. The fact that these "issues" are only now being asserted reveals this motion for what it is: a strategic attempt to disrupt the Plaintiffs' preparation of these wave cases.

Argument and Citation of Authority

Because this issue was thoughtfully considered and decided for purposes of these pelvic mesh MDLs more than three years ago, and because Defendants offer no compelling reason to overturn the pre-trial rulings that have governed this litigation for years other than their unsubstantiated claim of "unfairness," Defendants' motion should be denied.

[1] Ethicon was obviously well aware of the fact that Plaintiffs' counsel in all of these cases were meeting with doctors prior to depositions, and that Plaintiffs' counsel was discussing corporate documents during these meetings – just as has been done in the context of nearly every one of the other hundreds of depositions taken in these pelvic mesh MDLs since the MDL 2187 was transferred to this Court in 2010. If Ethicon believed that this was prohibited by any rule or law, they would have raised the issue before now.

Plaintiffs bear the burden of proof in this litigation, and therefore it is not only appropriate, but incumbent upon Plaintiffs' counsel to fully prepare their case by eliciting information bearing on the issues in this litigation from all available sources – particularly from the Plaintiffs' treating doctors. As Judge Stanley recognized in addressing the very issues presented in this motion more than three years ago, "lawyers would be derelict if they did not interview their witnesses before they took their testimony and if they did not show them relevant documents." (**Exhibit 1**, 21:12-19; 22:21-23). In her Order denying Bard's motion seeking identical limitations based on the same arguments raised by Ethicon here, Judge Stanley further observed that "[n]either a statute nor a rule suggests that such limits are appropriate; in fact it is accepted that attorneys are expected to prepare their witnesses for the rigors of giving testimony…. Contents of corporate documents and statements of sales representatives to treating physicians and surgeons are appropriate areas of inquiry as to whether full disclosure would have changed a doctor's mind about implanting a pelvic mesh product." (**Exhibit 2**, pp. 3-4).

Plaintiffs' doctors are key fact witnesses in these cases, and not just as relates to their knowledge regarding the Plaintiffs' medical conditions and/or diagnoses. By way of example, Plaintiffs' doctors generally had communication with Defendants' sales representatives relative to the devices at issue in this litigation. Plaintiffs should not be restricted from asking these doctors what they were told (or perhaps not told) about these products in the course of the Defendants' marketing efforts for these products. Also, the Plaintiffs' physicians implanted not only these individual Plaintiffs, but typically a number of other women with these products. As a result, these doctors may have dealt with other patients who have experienced complications. In the preparation of these cases, Plaintiffs should not be prevented from discussing with these physicians their knowledge about other product-related complications, including their

communications with the Defendants relating to such complications. Plaintiffs should not be precluded from discussing with the doctors whether and how they were instructed and/or trained by the Defendants to address product-related complications. Plaintiffs should not be limited in discussing with these doctors whether the frequency and severity of complications they experienced are consistent with the information they were provided by the Defendants – as well as information known to Defendants that may not have been provided to the doctors.

While Defendants complain that Plaintiffs have discussed such with their treaters, Plaintiffs should not be restricted from addressing the defenses presented in these cases relative to doctor fault. In every case in this MDL and the related pelvic mesh MDL's (irrespective of the product or manufacturer), the Defendants attempt to blame the plaintiff's injuries on one or more of her treating medical providers, if not on the plaintiff herself. The Defendants' "Master Answer" contains several defenses that point the finger directly at the Plaintiffs and/or their doctors. (*See, e.g.*, Dkt. No. 218-4 (Master Answer), Fortieth Defense; Forty-First Defense; Forty-Second Defense; Forty-Third Defense; Forty-Fourth Defense; Forty-Sixth Defense; Forty-Eighth Defense; Forty-Ninth Defense; Fiftieth Defense).[2] The doctors' skill and experience in implanting the subject devices will be scrutinized and dissected by the defense in every one of these cases. Therefore, Plaintiffs' counsel not only have the right, but an obligation to inquire

[2] As another example, at the September 2011 FDA hearing addressing serious concerns about the safety of transvaginal mesh devices, Ethicon's Worldwide Medical Affairs Director for Women's Health and Urology, Piet Hinoul, testified that the complications associated with these devices are always the result of either patient factors and/or doctor experience (i.e., it's not the product's fault), stating "One of the most important questions we need to ask ourselves is also why these adverse events are occurring. And the risk factors for mesh exposures are becoming more and more apparent. Several studies published this year show that hysterectomy, patient age, smoking, diabetes, and surgeon experience predispose patients to mesh exposure." (Excerpt of FDA hearing transcript attached hereto as **Exhibit 4**). Of course, blaming the patient's medical condition is at least indirectly pointing the finger at the physician for poor patient selection.

about their doctors' knowledge, training, experience and technique relative to these products, as well as the scope and substance of Defendants' physician training program and materials.

Perhaps most importantly, however, Plaintiffs should not be restricted in their ability to address the Defendants' failure to warn, and the related "learned intermediary" doctrine, about which issues the Plaintiffs' doctors are undeniably *the* critical fact witnesses. Under the learned intermediary doctrine, which is applied in most states, the Defendants will contend that the manufacturer's/seller's duty to warn generally runs to the doctor (the "learned intermediary") instead of to the patient. Thus, what the doctor was told – or *not* told – by the Defendants in light of the Defendants' knowledge at the time are important issues of fact.[3] Because, Plaintiffs contend, the Defendants had knowledge regarding the risks and complications associated with these products that they failed to disseminate to Plaintiffs' doctors, that is information that will bear on the failure to warn and the learned intermediary issues presented in most of these cases. Likewise, what the particular plaintiff's doctor would have done had he or she been made aware of all information known to the Defendants (whether or not he or she would have still implanted the product in light of such information, or whether he or she would have provided this information to the patient in providing an informed consent) are necessary inquiries in these cases. The only way for Plaintiffs to meaningfully address these issues in preparation is to ask the doctors "did you know 'x' and 'y' that Defendants knew," and "would it have made any difference in how you treated this patient if you had been provided this information?" It is

[3] As set forth in *In re: Avandia Marketing, Sales Practices and Prods. Liab. Litig.*, 817 F.Supp.2d 535, 547 (E.D.Pa.2011), "the adequacy of a warning [under several states' laws] is determined based on what a manufacturer knew or should have known about a given risk at the time a patient is prescribed the drug or the cause of action arose, and whether the label warned of that risk. A manufacturer is not excused if it remains purposefully ignorant of a particular risk. The duty to warn is thus a continuing one, and obligates a manufacturer to conduct research and otherwise investigate risks associated with its products, and then update warnings as appropriate."

entirely appropriate, indeed necessary, for Plaintiffs to address these important questions with Plaintiffs' treating physicians in preparing these cases.

Contrary to Defendants' assertions in their brief, there is nothing remotely unfair or untoward about a Plaintiffs' attorney speaking with his or her client's doctors about matters relevant to this litigation. Indeed, as Judge Stanley pointed out at the hearing on this issue, Plaintiffs' counsel would be "derelict" if they did *not* adequately explore these issues. While federal and state courts have routinely prohibited or at least restricted *defendants*' *counsel's* ability to communicate "ex parte" with a plaintiff's physician based on the confidential physician-patient relationship and/or the HIPAA Privacy Rule, 45 C.F.R. § 164.512,[4] plaintiffs have generally not been so restricted because the same concerns (confidentiality and patient privacy) are simply not present for the plaintiff's attorney. In the Philadelphia state court *In Re: Phen-Fen* litigation, the defendant filed a motion similar to that filed by Defendants herein, which was styled a "Motion to Preclude Inappropriate Communication with and Influencing of Treating Physicians." In denying such motion, the court in *In Re: Phen-Fen* noted that it was not empowered to limit plaintiffs' access to their doctors, and further that there was no factual support for the defendant's allegation of any improper influence. (A copy of the 1/8/08 Order from *In Re: Phen-Fen* is attached hereo as "**Exhibit 5**").[5] Similarly, in *In re: Kugel Mesh Hernia Repair Patch Litig.*, 2008 WL 2420997, *1 (D.R.I. 2008) , where the court rejected the

[4] A 2003 article in the American Journal of Trial Advocacy noted that "[n]ationally, the clear majority view is that such *ex parte* communications are disfavored in the law." D. Wirtes, et al., *An Important Consequence of HIPAA: No More Ex Parte Communications Between Defense Attorneys and Plaintiff's Treating Physicians*, 27:1 Am. J. Trial Advoc. at 5-6 (2003). This article catalogued the cases: in all, thirty-six states either banned *ex parte* interviews by defense counsel or had placed "such significant restrictions on them that they cannot truly be called *ex parte* communications." *Id.* (collecting citations).

[5] In February 2012, the defendant in the *Phen-Fen* state court litigation moved again to limit the scope of plaintiff's counsel's communications with their clients' doctors, and again, the court denied the motion. (A copy of the 3/26/12 Order denying "Defendants' Motion to Limit Communications with Treating Physicians" is attached hereto as "**Exhibit 6**.").

defendants' motion to communicate "ex parte" with plaintiffs' doctors, it was held that "the just option…is to protect the relationship between a doctor and patient by restricting defendants from conducting *ex parte* communications with plaintiffs' treating physicians but allowing plaintiffs' counsel to engage in *ex parte* interviews with those doctors who have not been named as defendants." The court in *In re: Kugel* relied expressly on Judge Fallon's earlier decision in *In re: Vioxx Prods. Liab. Litig.*, 230 F.R.D. 473, 477 (E.D.La. 2005), wherein Judge Fallon recognized that while this approach may initially appear "one sided and unfair," the defendant has various means to access information from the plaintiffs' doctors, such as medical records, product "census" data, "Plaintiff Profile Forms," and depositions. Through their marketing and training representatives, these Defendants have had the opportunity to provide these doctors with significant amounts of information about these products "ex parte." While Plaintiffs have no way to know what Defendants may or may not have told these doctors about these products, Judge Fallon noted in *In re: Vioxx*, *supra*, that "[a]s a practical matter, the Defendants already have information, including documentation, regarding what its representatives told the treating physicians about [the subject devices]. Therefore, the Defendants don't need the doctors to tell them in ex parte conferences what they already know."[6] Defendants' complaints of unfairness here are similarly ill-founded.

In opinions that are conspicuously absent from Defendants' briefing, two federal MDL Judges have considered and rejected arguments similar to those by Defendants here that plaintiffs' counsel should be restricted in their ability to meet with the plaintiffs' doctors. In *In*

[6] Defendants have included a brief excerpt from a pretrial hearing transcript with Judge Fallon in *Vioxx*, which snippet they represent indicates that Judge Fallon believed the plaintiffs' lawyers were abusing the pre-deposition meeting process. Contrary to the insinuation of Defendants' briefing, however, Judge Fallon never "revisited" his Order allowing Plaintiffs' to meet with their treating doctors, and no limitations or prohibitions were imposed on these meetings.

re: Yasmin and Yaz (Drospirenone) Marketing, Sales Practices and Prod. Liab. Litig., 3:09-md-01200 (S.D.Ill. 2011), the court rejected the defendants' requests to limit plaintiffs' counsel's ability to meet with their physicians, observing that "the Court is not aware of and the Defendants have not cited, any rule or controlling authority that prohibits an attorney from providing a witness with documents when engaged in permissible ex parte communications." (A copy of the 3/4/11 *In re: Yasmin* Order is attached hereto as "**Exhibit 7**"). The court in *In re: Yasmin* considered and expressly rejected the restrictions urged by the defense there, and ruled that plaintiffs' counsel could provide their clients' doctors with documents not previously seen by the doctors, including the defendant's internal documents, documents identified as confidential, research documents, scientific studies, and product warnings and labels. (**Exhibit 7**). Similarly, in considering the "Defendants' Motion to Define the Scope and Subject Matter of Plaintiffs' Ex Parte Contact With Treating Physicians" there, the court in the *Kugel* MDL concluded that "Defendants' proposed limitations are unnecessary and unworkable" and observed that "Defendants do not specifically identify any substantial prejudice or injustice resulting from the challenged contacts," and that the limitations proposed "would be difficult to police and may result in unproductive, 'side-litigation,' regarding the particulars of the discussions of these unrecorded, ex parte meetings." (A copy of the 1/12/12 *In re: Kugel* Order is attached hereto as "**Exhibit 8**").[7] Thus, the defense's attempts in *Kugel* to improperly limit plaintiffs' attorneys in communicating with their clients' doctors was soundly rejected.

[7] This pelvic mesh litigation has been on-going for years. The Bard MDL was created in 2010, and this MDL was transferred to this Court in 2012. There have been numerous Ethicon pelvic mesh cases prepared for trial, and several cases have gone to trial or resolved during or prior to trial. To change the rules at this juncture to so drastically affect the Plaintiffs' preparation of these cases for trial – including their preparation of these cases to date over the past few years – would cause undue and unwarranted prejudice to Plaintiffs.

More recently, in the *In re Mentor ObTape Transobturator Sling Products Liability* MDL, another federal MDL involving a pelvic mesh device, the Hon. Clay D. Land of the Middle District of Georgia denied a defense motion seeking to limit the scope of Plaintiffs' pre-deposition meetings with their treating physicians nearly identical to the present motion. (A copy of the 5/28/15 *Mentor* MDL Order is attached hereto as **Exhibit 9**). The MDL court in *Mentor ObTape* expressly adopted Judge Stanley's reasoning in her Order in the Bard MDL on this issue, stating "[t]he Court finds their rationale persuasive and adopts it." (*Id.*, p. 2). It is instructive to note here that Mentor Worldwide, LLC, the defendant in the Mentor ObTape MDL, is a wholly-owned subsidiary of Johnson & Johnson, one of the Defendants here. Thus, Defendants' failure to mention this recent MDL order in their briefing is inexplicable.

While urging this Court to disregard Judge Stanley's order which has governed this litigation for years and for countless doctor depositions, Defendants point to decisions from other courts that have purported to limit a plaintiff's counsel's ability to communicate with a plaintiff's doctors, describing this as some "emerging trend." (Dkt. No. 1707, p. 2 n. 1). First, it should be noted that with the exception of the *Actos* order entered by a California state court judge and the *In re: Pelvic Mesh* decision entered in the New Jersey state court, each of the cases relied upon by Ethicon were decided **prior to** Judge Stanley's hearing and order addressing this very issue. When these same cases were previously cited to and argued to Judge Stanley, Judge Stanley noted instructively as follows:

> I find the cases which have suggested that it's appropriate to put in limitations [on plaintiffs' ability to meet with doctors] to have offered less than substantial reasons in support of them. There's certainly no provision of the rules, as I've already said.

(**Exhibit 1**, 21:25-22:4).

The same remains true with respect to all of the cases cited by Defendants.

The Defendants' repeated complaints of "fairness" and "prejudice" are imagined and unsubstantiated. Again, these claims are based on nothing more than their own characterization of discussions prior to depositions taken long ago in cases where no issue of impropriety has ever been raised (including one case that was resolved after trial began). The only unfairness and prejudice would be if Plaintiffs were prohibited from these contacts, or limited in their ability to meet with these doctors. The Defendants, among the world's largest medical device manufacturers, have had extensive contact and communication with these doctors for years. The Defendants frequently tout their products to through sales calls, brochures, patient information booklets, websites, seminars and webinars. The Defendants' sales personnel make routine office visits to doctors, and regularly accompany doctors into the operating room to observe surgeries. These sales personnel treat doctors and their office staff to free meals and other perks. The Defendants host doctors at training sessions, reimbursing their travel expenses. The Defendants hire doctors as consultants, proctors and/or lecturers and pay them fees. The Defendants maintain a visible presence to doctors in their medical device industry advocacy role, including their active leadership role in AdvaMed (for example, as noted above, Ethicon's Worldwide Medical Affairs Director for Women's Health spoke on behalf of transvaginal mesh manufacturers before the FDA Panel investigating safety concerns related to these products in 2011). The Defendants are also members of physician societies and organizations, and regularly sponsor meetings of these doctor societies, which are attended by physicians in the field. [8] These

[8] Defendants work closely with these doctor societies to advocate and promote their products and viewpoints within the profession. For example, as the Court is aware, the American Urogyncologic Society (AUGS) and Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) has published a joint opinion paper, in consultation with its medical device industry members, touting the purported safety and efficacy of stress urinary incontinence slings. Every doctor in this field knows the defense's theories in this litigation; they are spelled out in this litigation advocacy piece, and in similar "papers" authored by industry-aligned physicians and doctor groups. Furthermore, while Defendants complain about Plaintiffs' counsel showing doctors corporate documents that post-date their

Defendants have spent untold dollars funding or sponsoring "papers" and "studies" regarding their products, and they utilize the same doctors who perform these "studies" to tout their products at these doctor society meetings. In light of their pervasive contact with and influence over these physicians and the medical profession generally, Defendants' complaints that an attorney could potentially influence a doctor's opinion by meeting for a few hours prior to giving an evidentiary deposition rings particularly hollow.

Defendants' complaint that Plaintiffs have "cherry-picked" unfavorable corporate documents to show these doctors, without providing appropriate "context," is equally disingenuous. These doctors were trained and sold on Defendants' products exclusively with Defendants' "cherry-picked" information – information intended for the sole purpose of persuading doctors to use these Defendants' products in their patients. Plaintiffs contend, and will prove in these cases, that these Defendants promoted and sold these products to these doctors without disclosing all of the information within their knowledge that bears on the products' safety and effectiveness, their risks, and the frequency, severity and duration of such risks. The Defendants' documents reflecting their knowledge of complications and the duration, frequency and severity of risks beyond what was disclosed in their warnings and promotional and training materials is the only "context" that these doctors are missing. In light of the fact that there have been multiple trials in this MDL, and in various state jurisdictions, the vast majority of these documents are now in the public domain, so there is no legitimate claim of "confidentiality" with respect to any of these documents. Defendants simply do not like the fact that the documents are being shown to doctors because they are damaging to their litigation interests. In 2012, when these same "cherry-picking" arguments were raised by Bard in MDL

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implantation surgeries, this 2014 AUGS/SUFU litigation opinion has been used exhaustively by the defense in these cases, including in nearly every doctor's deposition.

2187, Judge Stanley noted the import of what the defendant knew and when in terms of how it would impact the implanting doctors' medical decision-making, stating as follows:

> So, for example, if this [internal Bard corporate] document on [the undisclosed complication of] persistent delayed healing was, in fact a -- shall we say a scholarly or, at least, it's obviously scientific and technical to some degree, which was several years after the fact, then that is appropriate game for cross examination and I think any doctor would want to know what did Bard know and when did they know it and how did that – how did that work itself into the timeline of when the doctor implanted the mesh? What was Bard telling me when I was relying on their statements and what did Bard learn later or perhaps before?

(**Exhibit 1**, 22:11-20).

Defendants' argument that Plaintiffs could transform their treating doctors into experts, while by-passing the expert report requirements under Rule 26, is a red herring. Initially, Judge Goodwin has outlined the appropriate parameters of testimony from a treating physician: causation opinions and factual testimony relative to the learned intermediary issues presented by the defense.[9] To the extent a treating doctor is expected to offer any expert opinion regarding causation, the Federal Rules were amended in 2010 to expressly provide for written disclosures for such non-retained experts, rather than a full-blown expert report.[10] Plaintiffs intend to comply with the Federal Rules and with the Court's prior orders regarding expert disclosures for any non-retained experts, where applicable.

Conclusion

[9] "In sum, I **FIND** that (1) causation opinions, if formed in the course of treatment of the bellwether plaintiffs, and (2) fact testimony related to the learned intermediary issue, specifically, whether the treating physicians would have used the Avaulta products if they were given the warnings that the plaintiffs contend should have been given, should not be excluded. These opinions fall within the realm of proper testimony from treating physicians. I further **FIND** that (1) expert opinions, if any, on product design, (2) testimony regarding other patients and complications unrelated to the bellwether plaintiffs treated by the physician, and (3) other opinions formed outside of the treating physicians' care and treatment of the bellwether plaintiffs should be excluded. These latter opinions are fraught with reliability and relevancy issues." *In re C.R. Bard, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, 948 F.Supp.2d 589, 616-177 (S.D.W.Va.2013).

[10] In both the *Bard* and *Boston Scientific* MDLs, Plaintiffs have produced non-retained expert disclosures for treating physicians where applicable.

Plaintiffs should not be limited in their ability to properly prepare these cases and meet their burden of proof by restricting their ability to discuss matters relevant to these cases with important fact witnesses, their client's own treating doctors. Plaintiffs' counsel's discussions with their doctors are not only appropriate, but as Judge Stanley agreed, they are necessary. To the extent any Plaintiffs' doctor were to offer testimony that would fall within the Federal Rules' parameters of expert testimony, Plaintiffs will comply with the law regarding expert disclosures. Defendants' complaints about depositions taken in this MDL years ago, including in cases that were tried and/or settled with no issue ever being raised, speaks loudly to the validity of their newfound complaints here. Respectfully, these issues were briefed, argued and decided for purposes of these MDLs more than three years ago. There is nothing "new" that has occurred in this litigation that would invite the undoing of Judge Stanley's well-reasoned order on these issues in 2012. Hundreds of doctors' depositions have been taken throughout the various pelvic mesh MDLs, cases have been tried, and cases have been resolved. To change the rules that have long governed at this stage of this litigation would only cause unnecessary disruption, delay and confusion. Defendants' motion should be denied.

Dated: September 29, 2015.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 29, 2015, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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